

MHRA Submission-Ready Checklist:

Use this quick checklist before every submission to reduce risk and stay audit-ready.

1. Content Accuracy & Verification

Confirm text, numbers, and graphics **match across all files**.

Pay attention to dosage instructions, safety warnings, and labeling.

Use automated comparison tools for PDFs, labels, and IFUs.

3. Audit Trail Completeness

Track every change with time stamps and user details.

Keep reviewer comments and approvals **in the record**.

Be ready to show **exportable audit logs** on request.

2. Version Control & Consistency

Submit only the latest, **approved version**.

Eliminate duplicates or outdated drafts.

Align metadata with your SOPs and MHRA requirements.

4. GxP Compliance Evidence

Demonstrate that **processes align with GxP**.

Provide **validation records** and audit-ready evidence.

Ensure documentation is **traceable** and **defensible** in inspections.

Learn how TVT can help you stay compliant.



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